Mitchell E. Daniels, Jr.
Governor

Judith A. Monroe, M.D.
State Health Commissioner

Indiana State Department of Health

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DATE: April 1, 2009

TO: All Local Health Departments
Attn: Chief Food Specialist

FROM: A. Scott Gilliam, MBA, CP-FS
Manager, Food Protection Program

SUBJECT: Caraco Pharmaceutical Laboratories, Ltd.- Digoxin Tablets Recall

Suggested Action: **Class Unidentified : Caraco Pharmaceutical Laboratories, Ltd. Recall of All Lots of Digoxin Tablets Due to Size Variability; Recommend notification to establishments that may carry this product via phone, fax or e-mail.**

From the information provided by FDA, the product has been distributed in Indiana. Consumers with the products with the following NDC codes that are within expiration should return these products to their pharmacy or place of purchase. Please notify this office at 317-233-7360 if any recalled product is found.

Caraco Pharmaceutical Laboratories, Ltd. Announces a Nationwide Voluntary Recall of All Lots of Digoxin Tablets Due to Size Variability

Contact:
Daniel Movens: (313) 871-8400
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FOR IMMEDIATE RELEASE -- DETROIT, March 31, 2009 -- Caraco Pharmaceutical Laboratories, Ltd. (NYSE AMEX: CPD), a generic pharmaceutical company, announced today that all tablets of Caraco brand Digoxin, USP, 0.125 mg, and Digoxin, USP, 0.25 mg, distributed prior to March 31, 2009, which are not expired and are within the expiration date of September, 2011, are being voluntarily recalled to the consumer level. The tablets are being recalled because they may differ in size and therefore could have more or less of the active ingredient, digoxin. The recalled tablets were manufactured by Caraco Pharmaceutical Laboratories, Ltd. This recall is being conducted with the knowledge of the Food and Drug Administration.

Digoxin is a drug product used to treat heart failure and abnormal heart rhythms. It has a narrow therapeutic index and the existence of higher than labeled dose may pose a risk of digoxin toxicity in patients with renal failure. Digoxin toxicity can cause nausea, vomiting, dizziness, low blood pressure, cardiac instability, and bradycardia. Death can also result from excessive digoxin intake. A lower than labeled dose may pose a risk of lack of efficacy potentially resulting in cardiac instability. Consequently, as a precautionary measure, Caraco is recalling these tablets to the consumer level to minimize any potential risk to patients.

Consumers with the products with the following NDC codes that are within expiration should return these products to their pharmacy or place of purchase.

Product Identification

Caraco Digoxin 0.125 mg is a scored round biconvex yellow tablet imprinted with "437"

Caraco Digoxin 0.25 mg is a scored round biconvex white tablet imprinted with "441"

NDC Numbers:

Digoxin Tablets, USP, 0.125 mg
57664-437-88 (100-count)
57664-437-18 (1000-count)

Digoxin Tablets, USP, 0.25 mg
57664-441-88 (100-count)
57664-441-18 (1000-count)

Patients using Caraco's Digoxin tablets, USP, 0.125 mg or 0.25 mg, who have medical questions should contact their healthcare provider for additional instructions or guidance.

Retailers who have this product should return the product to their place of purchase. Retailers can call Caraco customer service at (800) 818-4555, Monday through Friday, 8:00 a.m. – 5:00 p.m. EST, for instructions on how to return the affected product or for any other inquiries related to this action.

Any adverse reactions experienced with the use of all affected product, and/or quality problems should also be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by Fax at 1-800-FDA-0178, by mail at Med Watch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch.

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